The Board of Pharmacy has received notice of the following product recall. The Board strongly encourages pharmacies to immediately review their quality assurance and recall policies and procedures to determine if any corrective action is required.

This is to inform you of a product recall by Cipla USA, Inc. for 4 lot (Lot# 5PB0183 (90mg), 5PB0172 (30mg), 5PB0164 (60mg) and 4PB0109 (30mg)) of Cinacalcet Hydrochloride tablets.

The start date of distribution is as follows:

Sr. No.	Product Name	NDC No.	FG Batch No.	Dates distributed
1.	Cinacalcet Hydrochloride tablets 90 mg	69097-412-02	5PB0183	May 28,2025 to October 31, 2025
2.	Cinacalcet Hydrochloride Tablets 30 mg	69097-410-02	5PB0172	May 07, 2025, to July 28, 2025
3.	Cinacalcet Hydrochloride Tablets 60 mg	69097-411-02	5PB0164	April 02, 2025, to May 08, 2025
4.	Cinacalcet Hydrochloride Tablets 30 mg	69097-410-02	4PB0109	April 23, 2024, to July 10, 2024

The product is labeled for and marketed by Cipla USA, Inc., bearing the NDC Numbers# 69097-412-02, 69097-411-02, 69097-410-02.

This recall has been initiated due to Out-of-specification results were observed for 'content of N-Nitroso Cinacalcet'

Based on Health Hazard Evaluation:

As part of the patient safety assessment, a Health Hazard Evaluation (HHE) performed and concluded that calculated patient exposure from the affected batches (maximum == 576 ng/day) remains well below both the AI x 6.7 interim threshold and the EMA-stipulated absolute upper limit of 1.5 µg/day.

Therefore, no immediate or short-term risk to patient safety is anticipated.